Home
Libby Site History
Our Mission & Goal
LATAG Bylaws
LATAG Policy & Procedure
Superfund Basics
Glossary
LATAG Meetings
Meeting Minutes
Environmental Results
Newsletter Archive
Press Release
Contact LATAG
Your Comments
News & Notice Signup
Become A Board Member
Risk Assessment Basics
OU-1 & OU-2 Commentary
OU-1 & OU-2 Summary
DEQ ACP

OU-1 & OU-2 Commentary

LATAG"s commentary on EPA's proposed plans for remediation of Operable Units 1 & 2.

Submitted on January 4, 2010

Introduction:

The Libby Area Technical Advisory Group requested Terry Spear, PhD, the group's technical advisor, to provide commentary on EPA's proposed plans for remediation of Operable Units 1 and 2. The LATAG Board has been working with Dr. Spear under contract this past year, bringing his expertise to assist the group in review of clean-up activities and make recommendations.

Dr. Spear is a professor of industrial hygiene at the University of Montana / Montana Tech., Butte, MT.

The LATAG Board has participated in the development of this document, and has reviewed and approved this final document generated by Dr. Spear for submission to the EPA in response to the request for commentary on proposed remedial plans for Operable Units 1 and 2 (OU-1 and OU-2.)

Review of the Proposed Plan to address environmental cleanup at Operable Units 1 and 2 (OU1 and OU2).

Submitted to the Libby Area Technical Advisory Group (LATAG)

by Dr. Terry Spear, Technical Advisor to the LATAG

Documents reviewed: Final Remedial Investigation Report, Operable Unit 1 – Former Export Plant Site, August 3, 2009; Final Feasibility Study Report, Operable Unit 1 – Former Export Plant Site, August 2009; Libby Asbestos Superfund Site OU1 – Former Export Plant, Proposed Plan for Public Comment, September 2009; Final Feasibility Study Report, Operable Unit – Former Screening Plant and Surrounding Properties, August 2009; Libby Asbestos Superfund Site OU2 – Former Screening Plant, Proposed Plan for Public Comment, September 2009.

November 9, 2009

The risks to residents of Libby and visitors to the area due to exposure to Libby amphibole (LA) asbestos poses a unique threat due to the multiple pathways of exposure. Residents and workers in Libby may be exposed through inhalation of LA in outdoor ambient air, inhalation

while engaged in outdoor activities that disturb a LA in soil (e.g., mowing, raking, digging), and inhalation of LA indoors at home or at work. Because of the multiple pathways of exposure, the risks of cancer and non-cancer adverse health effects must be reduced as low as possible in all Operable Units. It is my opinion that the proposed Records of Decision (RODs) for Operable Units 1 and 2 are premature and do not guarantee protection of public health because of the following:

1. **Uncertainties in risk assessment:** Uncertainty in risk assessment is increased when using dose-response information only from animal studies, using dose-response information from high doses (occupational) to predict adverse health effects from low exposure, and not considering increased susceptibility of special groups within the exposed population. Susceptible groups in Libby include children whose lungs are not fully developed until early adulthood, or immune-compromised individuals. Risk models may underestimate exposures to children because: (a) their lungs are still developing, (b) children are known to have faster breathing rates; (c) children's breathing zone is closer to the ground and thus more likely to breathe soil/dust contaminated with LA; (d) activity patterns for children may increase their airborne exposures. Children's increased levels of physical activity result in proportionally greater minute volumes, likely leading to increased dose; (e) added risk for childhood exposure relates to their longer span of life years which allows for a significant cumulative dose from low level LA exposure followed by latencies adequate to cause significant health effects.

1.

Current risk models may underestimate the risk associated with exposure to LA.
Risk models based on working populations do not address susceptible populations or brief exposures to high levels of asbestos. The current risk models do not adequately address risks associated with low-dose exposure to the mixed- LA seen in Libby. The shape of the exposure-response curve at low cumulative exposures is not known. Current risk models assume a linear relationship and the slope is largely derived from occupational cohorts with much higher exposure levels. Exposure estimates provided in the epidemiological reports used to derive the current risk models are often highly uncertain. The cancer unit risks derived by USEPA (1986) and USEPA (2008) are based on mortality statistics from the 1970's, and consequently may not be applicable to populations that are exposed to asbestos today. The risk of developing cancer from an exposure to asbestos has increased as life expectancy has increased. Thus, cancer risk predications based on the current method may be underestimating risk by up to 20%. Finally, the current risk models do not address the risks posed by fibers less than 5 micrometers (um) in length or less than 0.25 um in diameter. Air sampling data from Libby reported by several researchers indicate that the majority of airborne fibers are less than 5 um in length when analyzed by transmission electron microscopy.

2. **Lack of a reference concentration (RfC) for inhalation exposure to LA, including non-cancer risks of LA fibers less than 5 micrometers (um) in length and 0.25 um in diameter:** The occurrence of non-cancer effects are a significant human health concern in the Libby community and affect a large segment of the population (18%). These non-cancer adverse health outcomes maybe be more significant than cancerous effects and are not addressed by the current cancer risk models. Studies of former workers and residents provide strong evidence that exposure to LA results in an increased incidence of non-cancer adverse effects, and that these effects occur in some individuals who appear to have had only low exposure.

Animal and *in vitro* studies suggest that fibers less than 5 um in length may play a role in fibrosis. EPA risk assessments based on regulated (or PCME) fibers with lengths greater than 5 um and widths greater than 0.25 um could grossly underestimate exposure to short and thin fibers and lead to uncertainties in risk estimates. Approximately 50% of the fibers seen in Libby are less than 5 um in length and 30% are less than 0.25 um in diameter. To reduce uncertainties and address the most significant health concerns in Libby, the reference concentration (RfC) for inhalation exposure to LA should be based on TEM analysis, including characterization of short (< 5 um) and thin (<0.25 um) fibers, and the role these fibers play in causing non-cancer adverse health effects.

3. **Lack of epidemiology data in Libby:** The toxicity values (carcinogenic and non-carcinogenic) for the mix of amphiboles in LA are being derived from dose-response relationships for the first time. Dose-response information can be derived from a number of different studies which include human health effects when available as well as animal studies. It has been well established that when human health data is available, it provides the information that creates less uncertainty than when other methods are used. The National Toxicology Program (NTP) states that toxicology studies along with epidemiology studies are the best means available for identifying potential human hazards. To further reduce uncertainty in any Records of Decision in Libby, the risk of inhalation exposure to LA must be evaluated using epidemiological studies of the Libby community. Epidemiological studies, together with toxicological studies, are needed to assess the health effects of low-dose exposures to LA. These studies should include examination of family members of former mine workers, people with short-term high-dose exposures, people with long-term low-dose exposures, and children. In addition to epidemiological studies in Libby, EPA should consider recent case-control studies which provide evidence for increased mesothelioma and lung cancer risks at very low lifetime cumulative exposures to amphibole asbestos.

4. **Gaps in solid matrix sampling data quantification:** The current analytical methods for solid matrix sampling (i.e., soil sampling) are insufficient for cleanup decisions. The use of polarized light microscopy (PLM) for (a) identifying concentrations of Libby amphibole in environmental media (i.e., soils), and (b) basing cleanup strategies on these results is not protective of public health. It is important to note that the 1% rule is not derived from a risk assessment or any other type of health-based analysis; therefore, it does not ensure that airborne asbestos fibers re-suspended by disturbing these soils will be below levels protective of human health. It is well established that disturbing soil containing less than 1% LA can re-suspend fibers and generate airborne concentrations that may pose a risk to public health. Analytical methods are needed that will reliably measure Libby amphibole in soils at concentrations well below 1% .In recent unpublished research outside of OU3, bulk samples of ash were reported as Trace <0.5 - 1% when analyzed by TEM method EPA/600/R-93/116. When analyzed by ASTM Method D 5755-03, these same samples showed between 4 to12 million structures per gram for fibers < 5 microns and between 4 to 6 million structures per gram for fibers ≥ 5 microns. The limitations of expressing asbestos concentrations in % are obvious from the above example when concentrations reported as trace contain millions of fibers per gram.

The estimation of bulk asbestos content in soil at OU1 and OU2 is uncertain because the soil sampling protocol may not accurately quantify the concentration of LA. Based on the preponderance of short fibers in Libby, use of the PLM method for final clearance is not appropriate. Soil samples that are below the limit of detection by polarized light microscopy (PLM) techniques may show high levels of asbestos fibers by other types of

microscopic techniques (e.g., scanning electron microscope (SEM) or transmission electron microscopy (TEM)). In addition, for soils samples below the limit of detection by TEM analysis there is at least a 5% chance that the true value could be higher. Given the limitations of the analytical methods for identifying and quantifying LA in soils at OU1 and OU2, it is impossible to say that the pathways of exposure have been eliminated.

5. **Gaps in air sampling data quantification:** The development of improved air sampling and analytical methods for LA includes (a) reducing inter-operator and inter-laboratory variability of the current fiber analytical methods, (b) developing fiber analytical methods with improved resolution to visualize smaller diameter fibers to assure more complete fiber counts, (c) developing a practical analytical method to differentiate between airborne exposures to asbestiform fibers from the asbestos minerals and fiber-like cleavage fragments from their non-asbestiform analogs, (d) developing analytical methods to assess fiber durability, (e) evaluating the collection efficiency of LA, and (f) comparison of direct and indirect sample preparation methods.

   Because of the variability of LA in air, estimates of mean exposure concentrations are uncertain due to random variation between samples. Consequently, a large number of samples are required to ensure that the data are representative. In addition, risk calculations based on mean air concentrations rather than the 95th upper confidence level (UCL) represent a source of uncertainty. The lack of a method for calculating the 95th UCL could result in an underestimation of risk. Additionally, air-sampling data reported from a laboratory as non-detect are treated as zero. It is probable that some of these zero values contain LA that is not quantified. Finally, air-sampling data for LA represents only a point in time that may not be representative of exposure under various activities and environmental conditions.
   These limitations, together with the limited activity-based sampling at OU1 and OU2, make the proposed Records of Decision highly uncertain. Detailed site-specific monitoring with analyses by TEM for more a comprehensive consideration of site-specific conditions related to OU1 and OU2 is needed. Risk assessments based on estimated mean anticipated exposures in OU1 and 2 are not appropriate, and risk calculations should be based on concentrations expected for the greatest exposure scenarios anticipated in OU1 and 2.

6. **Gaps in exposure pathway quantification:** The relationship between LA contamination of soil and indoor dust to airborne concentrations of LA is poorly understood. Further research is needed to better define this relationship. Activity-based sampling, together with reliable sampling and analytical methods for LA in solid matrices (soils and dust) and air, should provide for a better understanding of the relationship between LA contamination of soil and indoor dust to airborne concentrations of LA. Exposure parameters of Central Tendency Exposure (CTE) and Reasonable Maximum Exposure (RME) can be uncertain and this uncertainty would be reduced by activity-based sampling.

   EPA has conducted activity-based sampling at residential and commercial properties in Libby in 2007 and 2008. Preliminary review of these results indicates that the current removal action level for LA in soil is likely to be revised to a lower concentration. Limited activity-based sampling has been done at OU1 and OU2. At OU1, only 8 activity-based sampling values are available, and these values may not be representative of the true long-term average exposure concentration for soil disturbances at OU1. The mean is highly uncertain and may be low. The data may underestimate exposure and risk because most of the ground was wetted to suppress dust dispersion before mowing.

   Extensive activity-based sampling, using TEM analysis to characterize the entire spectrum of exposures generated (size and type of amphibole), should be performed throughout the Libby Asbestos Site and within all Operable Units to determine potential cumulative exposure of residents to Libby amphibole. Activity-based sampling must be specific to each Operable Unit and used to simulate likely site activities and potential exposures associated with these activities. In addition to the collection of personal samples at appropriate breathing zone height, the activity-based sampling should include surface wipe samples of protective clothing worn and equipment used by the researchers. Research in the Libby area has demonstrated a strong potential for clothing and equipment contamination among people working with and around material contaminated with LA. This contamination may serve as a secondary source of exposure to those that work or recreate around contaminated material. In addition, family members, etc., not directly exposed to LA may be exposed while laundering contaminated clothing. Perimeter samples must be collected to document migration concurrent with the activity-based sampling. Background (control) samples must be collected concurrent with and upwind in general area as the activity-based sampling at a distance sufficient to prevent being influenced by the simulated activities. Soil moisture and wind data must be collected in conjunction with the activity-based sampling. The analytical data obtained must contain the full details on the particle size (length, width, mineral type) of all asbestos structures observed, so that these data can be used in prospective studies (including studies of low dose and childhood exposure) and cancer and non-cancer risk models.

7. **Gaps in cleanup efficacy data and elimination of exposure pathways:** Because trace levels or higher levels of LA are present in soil at OU1 and OU2 and in other areas throughout Libby, future exposure associated with disturbing on-site soil during construction or redevelopment events at these sites is a potential exposure pathway. In addition, trace levels or higher levels of LA are vulnerable to disturbance by various anthropogenic or natural activities. Consequently, residents can be potentially exposed to asbestos fibers released from asbestos-containing debris or soil due to disturbance by common human intrusive activities or natural processes (e.g., wind erosion, precipitation, and extreme changes in temperature) either now or in the future. Uncontrolled drainage of water from areas contaminated with LA may result in environmental dispersion of asbestos.

   Indoor stationary air monitoring performed at varying time periods following completion of cleanup actions at specific properties in Libby showed low airborne concentrations of LA following cleanup, and the level remained low for about a year. However, at some of the homes, there appeared to be an upward trend in airborne levels of LA, suggesting the potential for re-contamination. This indicates pathways of exposure still exist after the completion of cleanup activities. EPA should base clean-up targets on activities that have been shown to produce elevated concentrations by TEM analysis. Detailed site-specific monitoring using TEM methods are needed for more a comprehensive consideration of site-specific conditions related to OU1 and OU2 to assure that exposure pathways have been eliminated.

Summary

From the above discussion, it is clear that we still do not have enough information to estimate cancer and non-cancer risks from community exposures to LA associated with OU1

and OU2. Because of the complex multiple pathways of exposure to LA in the Libby area, and the lack of representative activity based sampling exposure data from the OU1 and OU2, uncertainties in exposure and risk of adverse health effects associated with OU1 and OU2 could result in an underestimate of cumulative cancer and non-cancer risks from exposure to LA in Libby.

The potential future health risks to Libby residents from exposure to LA is unknown because of uncertainties associated with: (a) the methods used to analyze asbestos; (b) the estimation of potential exposure to airborne asbestos from contaminated soils; (c) the lack toxicological information specific to LA; (d) the relative toxicity of short asbestos fibers (i.e., fibers <5 μm in length) in non-cancer health effects and (e) the lack of epidemiologic data evaluating the risk of adverse health outcomes associated with low-level, intermittent exposures to LA.

Before any Records of Decision are implemented in Libby, the uncertainties outlined above must be addressed:

(a) Improved analytical methods must be used to quantify levels of LA in both soil and air at OU1 and OU2 and throughout Libby.

(b) Conduct site-specific, activity-based field tests, during all seasons of the year, to assist in developing empirical relationships for exposure scenarios involving re-suspension of asbestos fibers from solid media (e.g., soil, dust) into air. Without knowledge of such relationships, the assurance of the elimination of exposure pathways and the protection of public health is uncertain. These limitations impede site-specific exposure assessment and risk characterization.

(c) Execute a comprehensive LA toxicity assessment to determine the effectiveness of the Libby clean-up actions and whether more actions are required. The toxicity assessment should include the effects of low dose exposure on susceptible populations, including children. Toxicology studies are also needed to adequately define the toxicity associated with short (<5 um) LA fibers since these fibers are predominant in Libby, including ambient air.

(d) Determine the reference concentration (RfC) for inhalation exposure to LA, including the risk contribution of LA fibers less than 5 micrometers (um) in length and 0.25 um in diameter.

(e) Sponsor epidemiologic studies employing the use of activity-based sampling results from Libby to allow the reconstruction of lower-bound estimates of exposure to LA associated with clinically detectable disease.

In policies issued by EPA in their Risk Assessment Guidance for Superfund, EPA is required to understand the cumulative risk from all exposures in the Libby area, and not just one OU. Recent case-control studies provide evidence for increased mesothelioma and lung cancer risks at very low lifetime cumulative exposures to amphibole asbestos.

The Risk Assessment Guidance document requires EPA determine the complete exposure pathways that exist for the Libby site. EPA is required to quantify the magnitude, frequency and duration of exposure for each pathway identified in Libby to determine cumulative risk. EPA is required to estimate reasonable maximum exposures for individual pathways. Given the complex multiple pathways of exposure to LA in the Libby area, the combination of exposures across pathways must be considered in cumulative risk estimates.

Exposure assessments must consider past, present, and future exposures. The Libby population has already had significant exposures to date that must be included in any benchmarks with consideration of future acceptable exposures. This is critically important for subpopulations that may be at increased risk from exposures to LA due to increased sensitivity, behavior patterns that may result in high exposure, and/or current or past exposures from other sources. Subpopulations in Libby that may be more sensitive to exposure to LA include infants and children, elderly people, and people with chronic illnesses.